

107TH CONGRESS
2D SESSION

S. 2818

To amend the Federal Food, Drug, and Cosmetic Act to ensure that there is competition in the pharmaceutical industry and increased access to affordable drugs.

IN THE SENATE OF THE UNITED STATES

JULY 29, 2002

Mr. GREGG introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to ensure that there is competition in the pharmaceutical industry and increased access to affordable drugs.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Timely Review and
5 Increased Access to Affordable Drugs Act”.

6 **SEC. 2. 30-MONTH STAY-OF-EFFECTIVENESS PERIOD.**

7 (a) IN GENERAL.—Section 505(j) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is
9 amended—

1 (1) in paragraph (2)(A)(vii)—

2 (A) by striking “a certification, the opinion
3 of the applicant and to the best of his knowl-
4 edge,” and inserting “a certification that, in the
5 opinion of and to the best knowledge of the ap-
6 plicant,”; and

7 (B) by inserting after “each patent” the
8 following: “published by the Secretary under
9 subsection (c)(2) at least 1 day before the date
10 on which the application is filed”; and

11 (2) in paragraph (5)—

12 (A) in subparagraph (B)(iii)—

13 (i) by inserting after “of a patent”
14 the following: “published by the Secretary
15 under subsection (c)(2) at least 1 day be-
16 fore the date on which the application is
17 filed”;

18 (ii) by striking “paragraph (2)(B)(i)”
19 each place it appears and inserting
20 “(2)(B)”;

21 (iii) by adding at the end the fol-
22 lowing: “If, in connection with an applica-
23 tion for approval of a drug under this sub-
24 section, the applicant provides an owner of
25 a patent notice under paragraph (2)(B)

with respect to the patent, and the owner of the patent fails to bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice is received, the owner of the patent shall be barred from bringing a civil action against the applicant with respect to the application.”;

(B) by redesignating subparagraphs (C) and (D) as subparagraphs (E) and (F), respectively; and

(C) by inserting after subparagraph (B) the following:

“(C) AVAILABILITY OF 30-MONTH PERIOD.—

“(i) IN GENERAL.—The 30-month period provided under subparagraph (B)(iii) shall be available only with respect to patents published by the Secretary under subsection (c)(2) at least 1 day before the date on which the application is filed.

“(ii) AMENDMENT OF APPLICATION.—If an application is amended to include a certification described in paragraph

1 (2)(A)(vii)(IV), the 30-month period pro-
2 vided under subparagraph (B)(iii) shall be
3 available with respect to the patent con-
4 cerning which the certification was made.

5 “(iii) SUBSEQUENT PATENTS.—

6 “(I) SEPARATE APPLICATION.—

7 Any patent published by the Secretary
8 under subsection (c)(2) subsequent to
9 the filing date but before approval of
10 an application under this paragraph
11 shall be addressed in a subsequent ap-
12 plication if the subsequent applicant
13 makes a certification described in sub-
14 paragraph (2)(A)(vii)(IV) with respect
15 to the patent, in which case the 30-
16 month period provided under subpara-
17 graph (B)(iii) shall be available to the
18 subsequently published patent.

19 “(II) REFERENCING INFORMA-

20 TION IN THE PREVIOUS APPLICA-
21 TION.—If a subsequent application is
22 filed, the Secretary shall permit the
23 applicant, to the extent that the Sec-
24 retary determines it to be appropriate,

1 to reference information submitted in
 2 the previous application.”.

3 (b) CONFORMING AMENDMENTS.—Section 505A of
 4 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 5 355a) is amended—

6 (1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i),
 7 by striking “(j)(5)(D)(ii)” each place it appears and
 8 inserting “(j)(5)(F)(ii)”;

9 (2) in subsections (b)(1)(A)(ii) and
 10 (c)(1)(A)(ii), by striking “(j)(5)(D)” each place it
 11 appears and inserting “(j)(5)(F)”;

12 (3) in subsections (e) and (l), by striking
 13 “505(j)(5)(D)” each place it appears and inserting
 14 “505(j)(5)(F)”.

15 **SEC. 3. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

16 Section 505(j)(5) of the Federal Food, Drug, and
 17 Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by sec-
 18 tion 2) is amended—

19 (1) in subparagraph (B)(iv), by striking sub-
 20 clause (II) and inserting the following:

21 “(II) the earlier of—

22 “(aa) the date of a final de-
 23 cision of a court in a civil action
 24 described in clause (iii) from

1 which no appeal has been or can
 2 be taken; or

3 “(bb) the date of a settle-
 4 ment order or consent decree
 5 signed by a Federal judge that
 6 enters a final judgment and in-
 7 cludes a finding that the patent
 8 that is the subject of the certifi-
 9 cation is invalid or not otherwise
 10 infringed;” and

11 (2) by inserting after subparagraph (C) the fol-
 12 lowing:

13 “(D) FORFEITURE OF 180-DAY EXCLU-
 14 SIVITY PERIOD.—

15 “(i) IN GENERAL.—The 180-day ex-
 16 clusivity period described in subparagraph
 17 (B)(iv) shall be forfeited if the applicant—

18 “(I) fails to market the drug
 19 within 30 days after the date on
 20 which the approval of the application
 21 for the drug is made effective under
 22 subparagraph (B)(iii);

23 “(II) fails to market the drug—

24 “(aa) within 30 days after
 25 the date of a final decision of a

1 court or the date of a settlement
2 order or consent decree in a civil
3 action described in subparagraph
4 (B)(iii); or

5 “(bb) if the application has
6 not been approved before the
7 date of such a decision, within 30
8 days after the date of approval of
9 the application;

10 “(III) withdraws the application;

11 “(IV) amends the application
12 from a certification under paragraph
13 (2)(A)(vii)(IV) to a certification under
14 paragraph (2)(A)(vii)(III);

15 “(V) fails to get tentative ap-
16 proval of the application within 30
17 months after the date on which the
18 application is filed, if the failure is not
19 caused by a change in the require-
20 ments for tentative approval of the
21 application imposed after the date on
22 which the application is filed; or

23 “(VI) enters into an agreement
24 with the owner of the patent—

1 “(aa) that is the subject of
2 the certification under paragraph
3 (2)(A)(vii)(IV); and

4 “(bb) that the Federal
5 Trade Commission determines
6 has violated the antitrust laws
7 (as defined in section 1 of the
8 Clayton Act (15 U.S.C. 12), ex-
9 cept that the term includes sec-
10 tion 5 of the Federal Trade Com-
11 mission Act (15 U.S.C. 45) to
12 the extent that that section ap-
13 plies to unfair methods of com-
14 petition).

15 “(ii) SUBSEQUENT APPLICANT.—If an
16 applicant forfeits the 180-day exclusivity
17 period under clause (i)—

18 “(I) a subsequent application
19 containing a certification period de-
20 scribed in paragraph (2)(A)(vii)(IV)
21 shall become effective immediately on
22 approval; and

23 “(II) the subsequent applicant
24 shall not be eligible for a 180-day ex-

clusivity period under subparagraph
(B)(iv).”.

SEC. 4. BIOEQUIVALENCE.

(a) IN GENERAL.—The amendments to part 320 of title 21, Code of Federal Regulations, promulgated by the Commissioner of Food and Drugs on July 17, 1991 (57 Fed. Reg. 17997 (April 28, 1992)), shall continue in effect as an exercise of authorities under sections 501, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 355, 371).

(b) EFFECT.—Subsection (a) does not affect the authority of the Commissioner of Food and Drugs to amend part 320 of title 21, Code of Federal Regulations.

SEC. 5. OVER-THE-COUNTER DRUGS.

Section 503(b)(3) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(3)) is amended—

(1) by striking “(3) The Secretary may by regulation remove drugs” and inserting the following:

“(3) REMOVAL OF CERTAIN DRUGS FROM REQUIREMENTS OF PARAGRAPH (1).—

“(A) IN GENERAL.—The Secretary may by regulation remove a drug”; and

(2) by adding at the end the following:

“(B) MISBRANDING.—A drug that is removed from the requirements of paragraph (1)

1 under subparagraph (A) shall be deemed to be
2 misbranded under paragraph (1) in a case in
3 which any person introduces the drug into
4 interstate commerce in accordance with the re-
5 quirements of paragraph (1).”.

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